PERFORMANCE VERIFICATION OF RAPID TESTS FOR THE DETECTION OF BIOTECH EVENTS

1. PURPOSE

This directive transmits procedures for verifying the performance of rapid tests used for detecting the presence of biotech events in grains. This service is provided under the authority of the Agricultural Marketing Act of 1946, as amended.

2. BACKGROUND

Biotechnology, or the use of recombinant DNA technology to alter or move genetic material into a plant to express a desired trait, is being applied to produce a new generation of disease and pest resistant grains and value-enhanced traits designed to meet specific market needs. At the same time, a rise in consumer preference for choice between biotech and non-biotech products is resulting in a non-biotech niche market.

To effectively market biotech and non-biotech crops, farmers and the food industry must have access to reliable detection methods to measure the value of improved quality attributes and to distinguish biotech from non-biotech crops. With reliable testing methods, all participants in the production and marketing system, from farm to end-user, can receive accurate information.

The Grain Inspection, Packers and Stockyards Administration's (GIPSA's) Federal Grain Inspection Service (FGIS) will evaluate rapid tests that are commercially available in the United States to test for the presence or absence of biotech products to facilitate the marketing of U.S. grain products, both domestically and internationally.

3. PROGRAM DEFINITIONS

Biotechnology-Derived Grains: Grains that have been enhanced through scientific techniques such as gene transfer (genetic engineering) to produce an organism with modified agronomic and/or quality characteristics.

Non-biotech Grains: Grains that have not been modified through biotechnology.

Microtiter Well ELISA Technology: Tests designed to detect the presence of biotech grains through the detection of a specific protein produced in the biotech grain. These tests provide quantitative and/or qualitative results using antibodies incorporated into microtiter wells and enzymatic, colorimetric reagents for detection.

Lateral Flow Strip ELISA Technology: Tests designed to detect the presence of biotech grains through the detection of a specific protein produced in the biotech grain. These tests generally provide qualitative results using antibodies and color reagents incorporated into a lateral flow strip.

Reference Materials: A material or substance, one or more properties of which are sufficiently well established, used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

Control Samples: Samples that do not contain any biotech grain.

Fortified Samples: Samples that have been prepared by mixing biotech grains with non-biotech grains to achieve a particular level, i.e., 0.1%, 1% and 5% by weight.

4. REQUEST FOR ADMISSION

To submit a test for verification, send the documentation (items a through g listed below) to:

Biotechnology Program Manager
Technical Services Division
Grain Inspection, Packers and Stockyards Administration/USDA
10383 N. Executive Hills Blvd.
Kansas City, MO 64153-1394

a. Manufacturer name and address

b. Manufacturer contact person

c. Telephone number

d. Fax number

e. E-mail address

f. Rapid test specifications identifying the parameters to be evaluated in the performance evaluation

(1) Test Format: Lateral Flow Strip, Microtiter Well Assay, or Other (specify)

(2) Matrix: Corn, Soya, Other (specify)

(3) Trait(s)/Event(s) Detected

(4) Qualitative or Quantitative Detection

(5) Operating Range

(6) Threshold of Detection or Quantitation (as appropriate)

5. DOCUMENTATION REVIEW

The Biotechnology Program Manager is the primary contact for manufacturers and is responsible for reviewing documentation, coordinating the rapid test evaluation process, and managing GIPSA's Rapid Test Performance Verification Program.

6. TEST EVALUATION PROCESS OVERVIEW

This protocol requires submission of specified data by the manufacturer and an evaluation by GIPSA staff to verify that the rapid test:

- Consistently detects the presence of the biotech grains in admixture, as indicated by manufacturer claims, and

- Performs in accordance with manufacturer claims with respect to threshold, qualitative and/or quantitative testing.

Rapid tests will be evaluated using samples that are free of biotech grain and samples that contain the trait(s) and/or event(s) specified by the manufacturer in the rapid test documentation. Only those rapid tests designed to detect the presence of biotech grains commercially available in the United States will be evaluated under this protocol.

Given that protein expression can vary significantly, data submitted by the manufacturer should reflect the effectiveness of the rapid test to detect the presence of the biotech grain at the lowest level of expression expected. GIPSA will evaluate all rapid tests at levels that approximate the lowest level of expression, based on available information.

7. REFERENCE MATERIALS

GIPSA may provide calibration samples when determined to be necessary or appropriate.

8. MANUFACTURER RESPONSIBILITIES

The manufacturer must provide GIPSA with the following:

a. Performance data on the rapid test with respect to the specified trait(s) and event(s) (see Section 9).

b. Equipment and/or materials, other than typical laboratory supplies, required for performing the rapid test.

c. Training in the use of the rapid test.

d. Rapid tests to be used by GIPSA for performance evaluation (see Section 11).

9. MANUFACTURER PERFORMANCE DATA SUBMISSION

Based on the manufacturer claims with respect to a particular rapid test, GIPSA will require the manufacturer to prepare and analyze specific sample sets to demonstrate the performance of the rapid test and submit this data to GIPSA for review. Generally, the samples described below will be the minimum required in the evaluation of all rapid tests:

a. Control Samples

(1) Thirty (30) control samples will be prepared using grain verified to be free of biotech grain.

(2) All thirty (30) samples will be independently analyzed as described in the operating instructions for the rapid test.

(3) A total of thirty (30) results will be reported to GIPSA, as described in the operating instructions for the rapid test.

b. Fortified Samples

(1) Thirty (30) fortified samples will be prepared at the minimum detectable level specified for the rapid test.

(2) All thirty (30) samples will be independently analyzed as described in the operating instructions for the rapid test

(3) A total of thirty (30) results will be reported to GIPSA, as described in the operating instructions for the rapid test.

c. Performance Verification at 18^{o} C and 30^{o} C

(1) Sample analyses at 18^{o} C

(a) Fifteen (15) control samples will be prepared using grain verified to be free of biotech grain.

(b) After equilibration of the samples and equipment for one hour at 18^{o} C, all fifteen (15) samples will be analyzed as described in the operating instructions for the rapid test.

(c) Fifteen (15) samples will be prepared at the minimum detectable level specified for the rapid test.

(d) After equilibration of the samples and equipment for one hour at 18^{o} C, all fifteen (15) samples will be analyzed as described in the operating instructions for the rapid test.

(2) Sample analyses at 30^{o} C

(a) Fifteen (15) control samples will be prepared using grain verified to be free of biotech grain.

(b) After equilibration of the samples and equipment for one hour at 30^{o} C, all fifteen (15) samples will be analyzed as described in the operating instructions for the rapid test.

(c) Fifteen (15) samples will be prepared at the minimum detectable level specified for the rapid test.

(d) After equilibration of the samples and equipment for one hour at 30^{o} C, all fifteen (15) samples will be analyzed as described in the operating instructions for the rapid test.

d. Cross Reaction with Other Expressed Protein

The manufacturer will provide data demonstrating the test does not falsely detect the presence of other proteins expressed by biotech grains. For example, data must be submitted showing a rapid test designed to detect the presence of the Cry1Ab protein does not detect the Cry1Ac and Cry9C proteins.

e. Other Samples

GIPSA may require submission of additional sample data based on a review of manufacturer claims with respect to the rapid test. For example, samples containing higher levels of biotech grain may be required for quantitative rapid test evaluation.

10. GIPSA EVALUATION OF SUBMITTED PERFORMANCE DATA

GIPSA will use the following criteria to assess the performance of the rapid test:

a. Control Samples. The manufacturer must classify all control samples correctly. No false positives will be allowed.

b. Fortified Samples. The manufacturer must classify all fortified samples correctly. No false negatives will be allowed.

c. Performance Verification at 18^{o} C and 30^{o} C

(1) Control Samples at 18^{o} C and 30^{o} C: All samples must be correctly classified as negative.

(2) Fortified samples at 18^{o} C and 30^{o} C: All samples must be correctly classified as positive.

d. Other Samples. The manufacturer must provide data on other sample analyses as requested by GIPSA to verify manufacturer claims.

After reviewing the data, GIPSA will advise the manufacturer that the rapid test met or did not meet GIPSA performance specifications. If the manufacturer can identify and correct deficiencies, they will be allowed to submit data a second time; otherwise, the manufacturer must wait a minimum of six months before resubmitting data for a GIPSA evaluation.

11. GIPSA PERFORMANCE EVALUATION

After determining the rapid test met performance specifications, GIPSA will make arrangements with the manufacturer for on-site training in the use of the rapid test. The GIPSA performance evaluation will be scheduled after training has been completed.

GIPSA will independently prepare control and fortified samples and analyze the samples according to the rapid test instructions using manufacturer-supplied rapid tests. The data will be evaluated against GIPSA performance standards and compared to data submitted by the manufacturer.

12. CERTIFICATE OF PERFORMANCE

Rapid tests that successfully meet GIPSA standards of performance will be awarded a Certificate of Performance. The Certificate of Performance will automatically expire three (3) years from the issue date. The manufacturer will be required to provide GIPSA performance data prior to the expiration date to have the Certificate of Performance renewed for an additional three years.

13. MANUFACTURER NOTIFICATION RESPONSIBILITIES

Manufacturers of rapid tests that have received a GIPSA Certificate of Performance must notify the Biotechnology Program Manager in writing when any changes or alterations are made to the rapid test, including changes in chemical reagents, equipment, or procedures. Failure to notify GIPSA of these changes will serve as grounds for immediate withdrawal of the GIPSA Certificate of Performance.

Correspondence regarding test alterations should be addressed to:

Biotechnology Program Manager
Technical Services Division
Grain Inspection, Packers and Stockyards Administration/USDA
10383 N. Executive Hills Boulevard
Kansas City, MO 64153-1394

/s/ Steven N. Tanner

Steven N. Tanner, Director
Technical Services Division